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EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT PAPER NUMBER

1638

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/778,018

Applicant(s)

MARTIN ET AL.

Examiner

Keith O. Robinson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 4-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date Dec 17, 2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-3) in the reply filed on August 11, 2005 is acknowledged. The traversal is on the ground(s) that there are two requirements for restriction, distinctness and a serious burden and that distinctness without a serious burden is not sufficient to justify restriction (see pages 2-3 of 'Remarks' filed December 9, 2005). This is not found persuasive because the Examiner has stated in the previous Office Action mailed August 11, 2005 that in addition to being distinct (as stated on page 7 of the Office Action) that searches of all the groups would in fact impose a serious search burden (see page 3, 2nd paragraph, page 4, 1st full paragraph and 3rd paragraph, page 5, 3rd paragraph, page 6, 2nd full paragraph, and page 7, 1st full paragraph).

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 4-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 9, 2005.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112, second paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Based on the claim language, it is unclear what is meant by "wherein the at least one molecular marker is markers Satt516 and Satt114". The claim does not particularly point out and distinctly claim the subject matter which Applicant regards as the invention. It appears that one marker is somehow made up of two markers or it seems that the claim may suggest that one or the other marker is required.

Claim Rejections - 35 USC § 112, first paragraph - Enablement

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it

pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to a method for determining the *Phytophthora sojae* resistance associated with the trait locus *Rps8* in soybean using molecular markers.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The assignment of molecular markers to particular traits is unpredictable and population-specific. In comparing results from other studies with that of their own, Lee et al. (Theor. Appl. Genet. 92:516-523, 1996) reported different genomic locations of putative QTLs from different populations and suggested that there may be population specificity of important QTLs. For example, Lee et al. found two putative independent markers associated with plant height on linkage group L, but reported that others did not find the same QTLs when using a different population (see, page 521, second paragraph).

Michelmore et al. (Proc. Natl. Acad. Sci. 88:9828-9832, 1991), van Ooijen et al. (Theor. Appl. Genet. 89:1007-1013, 1996), and Concibido et al. (Crop Sci. 37:258-264, 1997), teach that it is unpredictable whether any particular PCR-derived or RFLP molecular marker developed with one population of soybeans may be successfully

utilized with another population comprising the same species, or with interspecific hybrids.

van Ooijen et al. teach for example in Tables 2 and 3 on page 1009, Figures 1-2 on pages 1010-1011, and on page 1009, column 1, line 11 to page 1012, column 2, line 14, that it is unpredictable whether the order or even presence of an RFLP developed in one population derived from one set of parameters may be identified and used with a population defined from a different combination of parentals.

Michelmore et al. teach for example on page 9829, column 1, lines 15-20, that it is unpredictable whether the order or even presence of a RAPD developed in one population derived from one set of parentals may be identified and used with a population defined from a different combination of parentals.

Concibido et al. teach for example on page 260, column 1, line 16 to page 261, column 1, line 12, that when one set of RFLP markers developed from one population of soybeans produced from one set of parental genotypes were used with two other different populations of soybeans produced by two different crosses, that the same markers yielded only 36.2% or 40.3% polymorphism, and that the other markers were not polymorphic in these populations and could not be used.

Westman et al. (Theor. Appl. Genet. 96:272-281, 1998) teach for example in the Abstract on page 272, that SSR-derived microsatellite types of molecular markers particularly suffer from linkage disequilibrium effects, and are unpredictable for use from one plant population to another. Westman et al. teach for example on page 272, column 1, line 30 to page 293, column 1, line 15 that single sequence repeat (SSR)-primer

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based assays do not amplify across all related genotypes, and even if they do, the bands are often mistakenly misinterpreted as allelic when they are not. These results suggest that the use of markers for one population may not give the same results when used in another population and that such use of markers in marker-assisted selection is unpredictable.

Given the breadth of the claims and the unpredictability of assigning molecular markers to particular traits, it would require undue trial and error experimentation for one of skill in the art to use the invention as claimed.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Demirbas et al (Crop Sci. 41: 1220-1227, 2001).

The claims read on a method of determining the *Phytophthora sojae* resistance associated with the trait locus *Rps8* in soybean using molecular markers. Claim 3 is interpreted to read either marker Satt516 or Satt114.

Demirbas et al disclose a method of determining *Phytophthora megasperma* resistance associated with trait loci *Rps1*, *Rps2*, *Rps3* and *Rps4* in soybean using molecular markers (see page 1223, 2nd column to page 1226, 1st column, lines 1-6 and

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Tables 2-9). In addition, Demirbas et al disclose the use of marker Satt114 (see page 1225, Table 7) and that this marker is associated with linkage group F (see page 1224, 2nd column, 2nd paragraph and page 1226, 1st column, 2nd paragraph).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Demirbas et al (Crop Sci. 41: 1220-1227, 2001), in view of Cregan et al (Crop Sci. 39: 1464-1490, 1999).

The claim read on a method of determining the *Phytophthora sojae* resistance associated with the trait locus *Rps8* in soybean wherein at least one molecular marker

is marker Satt516 and Satt114. This claim has been interpreted to mean both marker Satt516 or Satt114 is to be used in the invention.

Demirbas et al teach a method of determining *Phytophthora megasperma* resistance associated with trait loci *Rps1*, *Rps2*, *Rps3* and *Rps4* in soybean using molecular markers (see page 1223, 2nd column to page 1226, 1st column, lines 1-6 and Tables 2-9). In addition, Demirbas et al teach the use of marker Satt114 (see page 1225, Table 7) and that this marker is associated with linkage group F (see page 1224, 2nd column, 2nd paragraph and page 1226, 1st column, 2nd paragraph).

Demirbas et al do not teach the use of molecular marker Satt516.

Cregan et al teach molecular marker Satt516 and that this marker is located on linkage group F. In addition, Cregan et al teach that *Rps3*, a gene associated with *Phytophthora* resistance is also on linkage group F (see page 1477, Figure 1).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to combine the teachings of Demirbas et al and Cregan et al to produce a method of determining the *Phytophthora sojae* resistance associated with the trait locus *Rps8* in soybean using molecular markers Satt516 and Satt114.

One of ordinary skill in the art would have been motivated to combine these teachings to produce a method of determining the *Phytophthora sojae* resistance associated with the trait locus *Rps8* in soybean using molecular markers because Demirbas et al teach that the use of markers can help plant breeders "select indirectly individuals in segregating populations that carry a gene for a favorable trait

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[and]...allows the breeder to bypass laborious and/or costly phenotypic screens" (see page 1220, 2nd paragraph, 2nd full paragraph).

In addition, one of ordinary skill in the would have reasonable expectation of success based on the success of Demirbas et al in producing a method of determining *Phytophthora megasperma* resistance associated with trait loci *Rps1*, *Rps2*, *Rps3* and *Rps4* in soybean using molecular markers

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

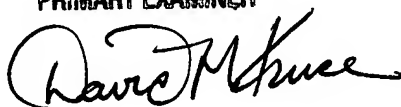
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15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

February 16, 2006

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "David H. Kruse", written in a cursive style.